UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

| | | |
|---|---|---|
| JONATHAN A. BLOOM,<br>Plaintiff,<br><br>v.<br><br>THOMAS E. PRICE, M.D.,<br>Secretary of the U.S. Department<br>of Health and Human Services,<br>Defendant. | )<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>) | Civil No. 5:16-cv-121 |

**DEFENDANT'S MOTION FOR ORDER AFFIRMING SECRETARY'S DECISIONS AND OPPOSITION TO PLAINTIFF'S MOTION TO REVERSE AND MEMORANDUM OF LAW**

Defendant Thomas E. Price, M.D., Secretary of the United States Department of Health and Human Services ("the Secretary"), by and through his attorney, Eugenia A.P. Cowles, Acting United States Attorney for the District of Vermont, respectfully moves for an Order affirming the Secretary's decisions, opposes Plaintiff's motion to reverse, and submits this memorandum of law in support thereof.

## I. INTRODUCTION

Plaintiff, Dr. Jonathan Bloom, brings this action pursuant to 42 U.S.C. § 405(g) (incorporated into the Medicare Act by 42 U.S.C. § 1395ff(b)(1)(A)),[1] to challenge three decisions by the Medicare Appeals Council ("Council") denying his requests for Medicare coverage of a Medtronic MiniMed continuous glucose monitor ("CGM") system, specifically, for a transmitter and disposable sensors for this CGM system. The Council's decisions, in each separate appeal, are the final decisions of the Secretary.

[1] Plaintiff alleges that jurisdiction is also conferred by 28 U.S.C. § 1331. Am. Compl. ¶ 14. However, "§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984) (quoting *Weinberger v. Salfi*, 422 U.S. 749 (1975)). *See also* 42 U.S.C. § 405(h) ("No action against the United States, or the [Secretary], . . . shall be brought under section 1331 . . . of title 28 to recover on any claim arising under this subchapter.").

Plaintiff's challenges to the final decisions dated November 13, 2015 (M-15-1505) and January 27, 2017 (M-16-10554) should be dismissed for lack of jurisdiction because the claims underlying each decision do not meet the amount in controversy required for judicial review of Medicare claims. With regard to the decision dated February 24, 2016 (M-15-4332), the Council properly determined that coverage should be denied because Plaintiff's CGM system does not fit within a Medicare benefit category—the Medicare benefit category for durable medical equipment ("DME")—and therefore, is non-covered. Administrative Record ("A.R.") M-15-4332, at 10-11. To the extent the Court declines to dismiss the decisions where jurisdiction is lacking and considers them on their merits, the Court should find that the Council appropriately determined coverage should be denied because Plaintiff's requested items did not fall within the DME benefit category. A.R. M-15-1505, at 27; A.R. M-16-10554, at 11.

Pursuant to 42 U.S.C. § 405(g), this Court's review is limited to determining whether the Secretary's decision is supported by substantial evidence. The Secretary reasonably interpreted the Medicare statute, regulations, and applicable policies, and his decision in each appeal is supported by substantial evidence in the applicable administrative record. Accordingly, the Council's decision in M-15-4332—as well as its decisions in M-15-1505 and M-16-10554, if determined to be properly before this Court—should be affirmed.

## II. APPLICABLE AUTHORITY

### A. The Medicare Statutory and Regulatory Scheme

1. Medicare, Generally

The Medicare statute (Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*.) is a federal health insurance program for the aged, the disabled, and persons suffering from end stage renal disease. The Medicare program is administered by the Centers for Medicare &

Medicaid Services ("CMS"), along with contracted private entities known as Medicare administrative contractors ("MACs"). *See* 42 U.S.C. § 1395u. This case involves reimbursement under Medicare Part B, 42 U.S.C. §§ 1395j–1395w-4.

2. Medicare Part B

Medicare Part B covers supplementary medical insurance for services such as doctors' visits, diagnostic testing, and certain medical supplies. *See* 42 U.S.C. §§ 1395k(a), 1395x(s). For an item or service to be reimbursable, it must fit within a defined benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and meet all applicable statutory and regulatory requirements. 42 U.S.C. §§ 1395k (outlining the scope of benefits under Medicare Part B to include "medical and other health services"), 1395x(s) (defining "medical and other health services"), 1395y(a)(1)(A) and (B) (reasonable and necessary). *See also Anghel v. Sebelius*, 912 F. Supp. 2d 4, 10 (E.D.N.Y. 2012); Medicare Program; Notice of Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55, 634, 55,635 (Sept. 26, 2003).[2]

MACs are responsible for determining whether items or services satisfy the Part B coverage requirements and, if so, the amount to be paid for them. 42 U.S.C. §§ 1395u, 1395kk-1. However, the Social Security Act prohibits payment "unless there has been furnished such information as may be necessary in order to determine the amounts due . . . ." 42 U.S.C. § 1395l(e). The regulations further clarify that it is a beneficiary's responsibility to furnish sufficient information to enable the contractor to determine whether payment is due and the amount of payment. 42 C.F.R. § 424.5(a)(6). Thus, beneficiaries have the burden to present

[2] While this Federal Register notice was later superseded, *see* Medicare Program; Notice of Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48,164 (Aug. 7, 2013), the subsequent notice did not alter the overarching requirements for Medicare coverage, including that an item must fit within a Medicare benefit category.

sufficient documentation, evidence, or testimony establishing that the items or services provided to them were covered by Medicare.

3. The Durable Medical Equipment Benefit

Pursuant to 42 U.S.C. § 1395x(s), "medical and other health services" are defined to include durable medical equipment ("DME") as a distinct benefit category for which payment may be authorized. 42 U.S.C. § 1395x(s)(6). DME includes "**blood** testing strips and **blood** glucose monitors for individuals with diabetes[.]" 42 U.S.C. § 1395x(n) (emphasis added). The Secretary has also established criteria through the regulations at 42 C.F.R. § 414.202, which more specifically define DME, as relevant to this case, as "equipment . . . that . . . [i] s primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202.

CMS has provided guidance on the regulatory criteria through its *Medicare Benefit Policy Manual* ("MBPM").[3] Chapter 15, Section 110.1 of the MBPM defines DME consistent with 42 C.F.R. § 414.202, and includes a description of "underlying policies for determining whether an item meets the definition of DME and may be covered." MBPM, Ch. 15, § 110.1 (effective Apr. 1, 2013). In elaborating on equipment which is "primarily and customarily used to serve a medical purpose," the MBPM states that "first-aid or precautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature" and, therefore, "are not considered covered DME." *Id.* at § 110.1-B-2.[4]

4. National and Local Coverage Determinations

While many coverage determinations are made on a case-by-case basis, Congress has

[3] CMS Pub. 100-02, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html.

[4] The MBPM does qualify that "[s]pecified items of equipment may be covered under certain conditions even though they do not meet the definition of DME because they are not primarily and customarily used to serve a medical purpose[.]" *Id.* at § 110.1-B-3. "These items would be covered when it is clearly established that they serve a therapeutic purpose[.]" *Id.*

authorized the Secretary to issue binding National Coverage Determinations ("NCDs"). *See* 42 U.S.C. § 1395y(l). A NCD is "a determination by the Secretary with respect to whether a particular item or service is covered nationally . . . ." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1062(a). NCDs are binding on the MACs that process claims, on Administrative Law Judges ("ALJs") reviewing beneficiary claims, and on the Medicare Appeals Council ("Council"). 42 C.F.R. § 405.1060(a)(4).

The Medicare statute also authorizes MACs to issue Local Coverage Determinations ("LCDs") that identify when particular items or services will or will not be covered in the contractor's jurisdiction. 42 U.S.C. § 1395ff(f)(2)(B). LCDs do not address all Medicare coverage criteria,[5] but "specify under what clinical circumstances a service is considered to be reasonable and necessary." *Medicare Program Integrity Manual* ("MPIM"), CMS Pub. No. 100-08, Ch. 13, § 13.1.3 (effective Jan. 1, 2012), http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

### B. Medicare Coverage of Home Blood Glucose Monitors and Non-Coverage of Non-Theraputic Continuous Glucose Monitors

Coverage for home (or traditional) blood glucose monitors is discussed in NCD 40.2, Home Blood Glucose Monitors. *See* A.R. M-15-4322, at 264; A.R. M-16-10554, at 55-59; *see also* Medicare Program; Special Payment Limits for Home Blood Glucose Monitors, 60 Fed. Reg. 3405 (Jan. 17, 1995) (explaining that "[s]tandard home blood glucose monitors allow

[5] Until the Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. 106-554, Local Medical Review Policies ("LMRPs") contained the information now found in LCDs. LMRPs were "contractor-specific policies that identify the circumstances under which particular items or services will be (or will not be) considered covered and correctly coded," and contained any or all of the following: coding provisions; benefit category provisions; statutory exclusion provisions; and payment prohibitions based on the determination that an item or service is not reasonable and necessary. Medicare Program; Final Rule, Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Today, information not pertinent to whether an item is reasonable and necessary, such as benefit category and coding guidelines, is included in "Policy Articles" that relate to an associated LCD. *See* MPIM, Ch. 13, § 13.1.3.

individuals to measure their blood glucose and, then, alter their diets or insulin dosages to ensure that they are maintaining an adequate blood glucose level"). Additionally, NCD 280.1, Durable Medical Equipment Reference List, discusses coverage criteria for certain types of equipment, including blood glucose monitors. *See* A.R. M-16-10554, at 55-59; NCD Manual, Ch. 1, Part 4, § 280.1 (effective May 5, 2005). NCD 280.1 explains that blood glucose monitors are "[c]overed if patient meets certain conditions (see §40.2 of the NCD Manual)." *Id.* Regarding equipment not specifically discussed, such as a continuous glucose monitoring system, NCD 280.1 directs that the MAC "ha[s] the authority and responsibility for deciding whether those items are covered under the DME benefit." *Id.* [6]

NHIC, Corp. ("NHIC"), the Medicare DME contractor for Plaintiff's jurisdiction, has issued LCD L11530 and Policy Article A33614 (both documents retired Sept. 30, 2015) and LCD L33822 and Policy Article A52464 (both documents effective Oct. 1, 2015), also addressing blood glucose monitors. *See* A.R. M-16-10554, at 290-314.[7] "[T]he criteria for 'reasonable and necessary'"[8] outlined in LCD L11530/L33822 relate to metered, home blood glucose monitors that require a beneficiary to place a blood sample, generally obtained using a lancet or fingerstick, on a reagent strip before placing it into the monitoring device which processes and reads the strip. A.R. M-16-10554, at 299-300. Along with the blood glucose

[6] NCDs are publicly available either through the Medicare Coverage Database, CMS.GOV, https://www.cms.gov/medicare-coverage-database, or the *Medicare National Coverage Determinations Manual* ("NCD Manual"), CMS Pub. No. 100-03, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html. The administrative records for the final decisions at issue in this appeal do not contain full copies of the NCDs, 40.2 and 280.1, referenced in this section. However, these documents are discussed in various places throughout the three administrative records.

[7] Only the administrative record for M-16-10554 contains copies of LCD L11530 and Policy Article A33614, which were retired prior to Plaintiff's request for coverage in that appeal. However, the newer versions of these documents are substantially similar to the prior versions. *See* A.R. M-16-10554, at 209. Full copies of the newer versions are publicly available online through the Medicare Coverage Database, located at https://www.cms.gov/medicare-coverage-database. *See also infra* note 13.

[8] LCD L11530/L33822 qualifies, however, that "[f]or any item to be covered by Medicare, it must . . . [also] be eligible for a defined Medicare benefit category . . . [and] meet all other applicable Medicare statutory and regulatory requirements." A.R. M-16-10554, at 299.

monitor itself, the LCD explains that Medicare will cover related supplies, including lancets and test strips, if the reasonable and necessary criteria are met. *Id.* at 300. Policy Article A33614/A52464 contains coding and benefit category information related to Medicare coverage of glucose monitors. A.R. M-16-10554, at 290-97. Policy Article A33614/A52464 also addresses continuous glucose monitoring ("CGM") systems, and indicates that "[c]ontinuous glucose monitors . . . are considered precautionary and therefore non-covered under the DME benefit." *Id.* at 291.

A CGM system (or simply, "CGM") is functionally different from a traditional blood glucose monitor. A CGM consists of a disposable sensor, a transmitter, and a receiver. A CGM continually measures an individual's **interstitial** (i.e., tissue) glucose level, not the individual's **blood** glucose level. The device then alerts the individual that it may be appropriate to utilize a home blood glucose monitor to determine if a therapy adjustment may be necessary. *See, e.g.*, A.R. M-15-4332, at 238, 540. Prior to December 2016, no CGM was approved by the Food & Drug Administration ("FDA") as a replacement for traditional blood glucose monitoring. *See* A.R. M-16-10554, at 16-17 (stating the Dexcom G5 Mobile CGM System is "the first FDA-approved [CGM] system that can be used to make diabetes treatment decisions without confirmation with a traditional fingerstick test"). Though the FDA had previously approved a handful of CGMs, such as the Medtronic MiniMed CGM utilized by Plaintiff, for limited purposes, these devices were not FDA-approved to take the place of traditional blood glucose monitoring.[9] Rather, these systems were approved to be used along with traditional blood glucose monitoring, and indeed, were reliant upon traditional blood glucose monitor readings for

[9] *See also* A.R. M-16-10554, at 83-84 (describing FDA-approval of a Medtronic "closed looped system," which functions as an artificial pancreas as opposed to a CGM). As Plaintiff has described, his CGM is "not an artificial pancreas." A.R. M-15-4332, at 385.

the purpose of making accurate treatment decisions in managing an individual's diabetes.[10] *See, e.g., id.* at 496, 523, 540.

**C. The Medicare Appeals Process**

A beneficiary may appeal from the denial of a claim for Medicare benefits.[11] *See* 42 U.S.C. § 1395ff(b); 42 C.F.R. Part 405, Subpart I. The first level of appeal available after a secondary review by the contractor is an on-the-record review by a qualified independent contractor ("QIC"). 42 C.F.R. § 405.960. If the beneficiary is dissatisfied with the QIC's decision, the beneficiary has the right to request an ALJ hearing. 42 C.F.R. § 405.1000(a). However, a hearing with an ALJ can happen only if the beneficiary seeks a certain amount from Medicare, called the "amount in controversy" ("AIC"), as adjusted for inflation. 42 U.S.C. §1395ff(b)(1)(E)(iii); 42 C.F.R. § 405.1006(b)(1). For calendar years 2015 and 2016, the AIC threshold for ALJ review was $150. 80 Fed. Reg. 57,827, 57,828 (Sept. 25, 2015). For 2017, this amount increased to $160. 81 Fed. Reg. 65,651, 65,652 (Sept. 23, 2016).

The ALJ's decision is binding unless the beneficiary appeals the decision to the Council, or the Council reviews the case on its own motion. 42 C.F.R. § 405.1048. The Council limits its review to "exceptions raised by the party in the request for review," except where a beneficiary

[10] While not applicable to the coverage requests at issue here, which predate the ruling, CMS issued Ruling No. 1682-R in January 2017. There, CMS stated that "Medicare . . . does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." CMS Ruling No. 1682-R, at 6-7 (Jan. 12, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf. However, CMS did recognize the FDA's recent approval of a "'therapeutic' CGM," the Dexcom G5 mobile CGM, meaning that the system could function as a "replacement of blood glucose monitors for diabetes treatment decisions." *Id.* at 7. CMS explained that therapeutic CGMs "provide information that can be used to make diabetes treatment decisions [and, therefore,] meet the definition of DME." *Id.* In contrast, "'non-therapeutic' CGMs," which have only been FDA-approved as "adjunctive devices," do not meet this definition. *Id.*

[11] The Medicare statute and regulations also permit challenges to LCDs. *See* 42 C.F.R. Part 426. Where another beneficiary sought to challenge Policy Article A33614/A52464, the Departmental Appeals Board ("DAB") ruled that the Policy Article was not an LCD and, therefore, that it was not reviewable. Consequently, the DAB reversed the ALJ's holding below, including his finding that the statement regarding CGMs articulated in the Policy Article was invalid, and dismissed the case. *See LCD Complaint: Glucose Monitors*, DAB 2782 (Apr. 10, 2017), *available at* https://www.hhs.gov/sites/default/files/dab-2782.pdf. To the extent that Plaintiff relies on the ALJ's holding, that reliance is misplaced.

is unrepresented. 42 C.F.R. § 405.1112(c). In rendering their decisions, the ALJ and the Council "are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a).

The Council's decision is the final decision of the Secretary, and is subject to judicial review if the beneficiary files an action in federal district court within 60 days of receiving notice of the decision, 42 C.F.R. § 405.1130; 42 C.F.R. § 422.612; however, a separate AIC must be met for a beneficiary to obtain judicial review. 42 U.S.C. § 1395ff(b)(1)(E)(i); 42 C.F.R. §§ 405.1006(c)(2). This amount, originally $1,000, is also annually adjusted for inflation. *See id.* During calendar year 2016, when Plaintiff filed this lawsuit challenging the final decisions in M-15-4332 and M-15-1505, the AIC required for judicial review was $1,500. 80 Fed. Reg. at 57,828. For calendar year 2017, when Plaintiff amended his lawsuit to also challenge the final decision in M-16-10554, the AIC rose to $1,560. 81 Fed. Reg. at 65,652.

## III. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff is a Medicare beneficiary with type 1 diabetes and a history of hypoglycemia. A.R. M-16-10554, at 137, 155, 159. Plaintiff has used a CGM system since 2006, prior to enrolling in the Medicare program in 2009. A.R. M-15-1505, Hearing Transcript, at 6, 8; A.R. M-16-10554, at 160. Plaintiff uses a Medtronic MiniMed CGM with insulin pump. A.R. M-15-4332, at 382; A.R. M-15-1505, Hearing Transcript, at 9-10; A.R. M-16-10554, at 144, 159. Plaintiff's CGM system is comprised of multiple parts, including a disposable sensor "put in with a needle" "and a transmitter [that] is hooked up to the sensor." A.R. M-15-4332, at 379-80. The disposable sensors last for six days. *Id.* at 391. Even when using his CGM system, Plaintiff must monitor his blood glucose level via traditional fingerstick monitoring. A.R. M-15-4332, at

385; A.R. M-15-1505, Hearing Transcript, at 12; A.R. M-16-10554, at 523.

**A. Council Decision No. M-15-4332 Dated February 24, 2016**

Plaintiff requested Medicare coverage for a transmitter, furnished on June 27, 2014, and disposable sensors for his Medtronic MiniMed CGM system, furnished on March 19, 2014 and June 18, 2014. A.R. M-15-4332, at 168, 314, 316. The total of these items was $1,976. *Id.* Plaintiff's requests were denied at all levels of the administrative appeals process. *See id.* at 89, 260. Plaintiff appealed these denials to the Council.[12] *See id.* at 3-7.

In a decision dated February 24, 2016, the Council upheld the denial of Plaintiff's requests for coverage. *Id.* at 3. Looking to NCD 280.1 and 40.2, the Council first found that neither NCD specifically addressed CGMs. *Id.* at 9. The Council then asked "whether the contractor ha[d] issued a relevant LCD and/or related policy article that was in effect on the date of service at issue." *Id.* The Council explained that "the contractor . . . had published LCD L11530 and related Policy Article A33614, both entitled 'Glucose Monitors.'" *Id.* The Council found that the LCD contained language that pointed to "[t]he Non-Medical Necessity Coverage and Payment Rules section of the Related Policy Article[,] [which] contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified." *Id.* at 10. Considering Policy Article A33614, the Council found that the document "makes clear that [Plaintiff's] CGM items do not meet the definition of DME because they are precautionary." *Id.*

The Council discussed the programmatic requirements informing the Policy Article's statement on CGM systems—in particular, the regulatory requirement that DME "primarily and

[12] These requests for coverage were originally the subject of two separate ALJ decisions. However, the Council permitted Plaintiff to challenge the two unfavorable decisions in a consolidated appeal. *See* A.R. M-15-4332, at 3-4, 13-14.

customarily serve[s] a medical purpose." 42 C.F.R. § 414.202. The Council stated:

> While the term 'precautionary' is not a statutorily defined term, it refers to the requirement that DME must itself serve a medical purpose. Where the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, but not for a primary medical purpose.

A.R. M-15-4332, at 10 (emphasis in original). The Council considered Plaintiff's hearing testimony and took judicial notice of the Medtronic website. *Id.* at 10-11. In doing so, the Council noted that traditional blood glucose monitoring is still required for individuals using a CGM "to check blood glucose levels . . . before therapy adjustment." *Id.* at 11. Consequently, "the CGM does not substitute for the existing means of controlling insulin usage, or measure blood glucose directly, . . . [but] merely provides an added precaution and does not itself serve a primary medical purpose." Given these undisputed characteristics, *see id.* at 10, the Council found no basis to depart from the Policy Article's conclusion that the CGM of the type used by Plaintiff, including the requested transmitter and sensors, did not qualify as DME. *Id.* at 10-12.

**B. Council Decision No. M-15-1505 Dated November 13, 2015**

Plaintiff requested coverage for a 30-day supply of disposable sensors for his CGM furnished on August 6, 2014. A.R. M-15-1505, at 116. The total cost for the sensors was $473. *Id.* Plaintiff's request was denied at the reconsideration and QIC levels before an ALJ issued a decision granting Plaintiff coverage. *Id.* at 38. CMS referred the ALJ's decision to the Council, which undertook to review the decision on its own motion. *Id.* at 23, 29-30.

On November 13, 2015, the Council reversed the ALJ's decision, stating that "the ALJ erred as a matter of law by analyzing whether CGMs are medically reasonable and necessary, but not the issue presented of whether CGMs are covered under the DME benefit." *Id.* at 23. Given the criteria specified in 42 C.F.R. § 414.202, "the first step in the analysis [of Medicare coverage] require[d] consideration of whether an item or device meets the definition of DME."

*Id.* "Only if the device meets the definition of DME, does the analysis then proceed to determine whether the device is medically reasonable and necessary for the beneficiary in a particular case." *Id.* In the absence of an NCD that specifically addressed CGMs, which the Council emphasized "are not blood glucose monitors," *id.* at 25 (emphasis in original), the Council turned its attention to the potential existence of an applicable LCD. *Id.* The Council ultimately turned to Policy Article A33614, and to an analysis of its statement that CGMs "'are considered precautionary and therefore non-covered under the DME benefit.'" *Id.*

The Council grounded its decision in the fact that not only does a CGM system not directly measure blood glucose, but relatedly, that it "is not FDA approved as a substitute for a conventional reagent test strip." *Id.* Thus, the Council agreed regarding the "precautionary" nature of CGM systems and concluded that they do not qualify as DME; "[w]here the beneficiary must still use another device to accomplish the medical purpose at issue, it is essentially used as an additional precaution, . . . not for a primary medical purpose," as required by the regulatory criteria. *Id.* at 27 (also citing Plaintiff's testimony before the ALJ that "the CGM device is used as a guide for his blood glucose levels but is not an 'absolute,'" and that he still must use traditional glucose monitoring in order to measure his blood glucose levels). *See also* A.R. M-15-1505, Hearing Transcript, at 12.

**C. Council Decision No. M-16-10554 Dated January 27, 2017**

Plaintiff requested coverage for a 90-day supply of disposable sensors for his Medtronic CGM, furnished on January 4, 2016. A.R. M-16-10554, at 317. The total for these items was $1,419. *Id.* Plaintiff's request was denied at the first three levels of administrative review, and he appealed the adverse ALJ decision to the Council. *See id.* at 104. Plaintiff was represented by an attorney during the ALJ and Council proceedings, and submitted several studies regarding

the efficacy of CGM systems written between the mid-2000s and mid-2010s. *See id.* at 455-801 ("Exhibit 1" during the administrative proceedings).

In a January 27, 2017 decision, the Council accepted the ALJ's conclusion that "Medicare does not cover and pay for the CGM sensors at issue . . .," but modified the ALJ's findings to clarify the basis for denial. *Id.* at 4. The Council discussed the DME criteria and the functionality of Plaintiff's CGM system. *See id.* at 4-5. Looking to the studies submitted by Plaintiff, the Council emphasized that a CGM still required users "to continue using multiple daily fingersticks to make diabetes treatment decisions and to adjust the insulin needed." *Id.* (citing sources). The Council concluded that because "the CGM system in this case . . . does not substitute for the existing fingerstick method of measuring blood glucose levels and controlling insulin usage, . . . any component parts merely provide an added precaution but do not serve an essential medical purpose and thus do not satisfy the regulatory definition of DME." *Id.*

## IV. STANDARD OF REVIEW

Judicial review of a final administrative decision regarding claims for benefits under the Social Security Act is authorized by 42 U.S.C. § 405(g). The Court's review is to be based on the pleadings and the transcript of the administrative record for the decision under review. *See* 42 U.S.C. § 405(g); *Mathews v. Weber*, 423 U.S. 261, 264 (1976). Through this action, Plaintiff seeks judicial review of three final decisions supported by three distinct administrative records.[13]

[13]As discussed below, Plaintiff did not aggregate these claims at the administrative level. Plaintiff's brief impermissibly blends the administrative records in order to support all of the claims for Medicare coverage at issue in each final decision. *See* Plaintiff's ("Pl.'s") Brief ("Br.") at 14-20. Plaintiff also seeks to rely on materials that are not contained within any of the three administrative records. *See, e.g.*, Pl.'s Br. at 17-18 (citing "a cursory review of . . . numerous coverage decisions"). Under 42 U.S.C § 405(g), the Court's review of a final decision of the Secretary should be restricted to the administrative record underlying that decision. *See, e.g., Mathews*, 423 U.S. at 264 (in an action under § 405(g), "[t]he court may consider only the pleadings and the administrative record . . ."); *Anderson v. Sebelius*, No. 1:09-cv-16, 2009 WL 5171089, *2 (D.Vt. Dec. 18, 2009). The Court may only consider additional evidence that was not part of the administrative record pursuant to sentence six, which authorizes remand for consideration of additional evidence where the evidence is "new," "material," and there is "good cause for

"The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g) (incorporated into the Medicare statute by 42 U.S.C. § 1395ff(b)). Thus, the Secretary's final decision may only be set aside if based upon legal error or not supported by substantial evidence. *See Berry v. Schweiker*, 675 F.2d 464, 467 (2d Cir. 1982); *Townley v. Heckler*, 748 F.2d 109, 112 (2d Cir. 1984) (explaining that conclusions of law are reviewed *de novo*). Substantial evidence "'means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Berry*, 675 F.2d at 467 (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)).

The Secretary's final decision is afforded considerable deference; the reviewing court "'may not substitute its own judgment for that of the Secretary, even if it might justifiably have reached a different result upon a *de novo* review.'" *Jones v. Sullivan*, 949 F.2d 57, 59 (2d. Cir. 1991) (quoting *Valente v. Sec'y of Health and Human Servs.*, 733 F.2d 1037, 1041 (2d. Cir.1984)). Accordingly, if supported by substantial evidence, the Secretary's decision must be upheld even where there is substantial evidence supporting the plaintiff's position. *See Schauer v. Schweiker*, 675 F.2d 55, 57 (2d Cir. 1982). "[T]he claimant bears the burden of proving [his] entitlement to Medicare coverage." *Keefe on Behalf of Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995) (citing *Friedman v. Sec'y of the Dep't of Health and Human Servs.*, 819 F.2d 42, 45 (2d Cir. 1987)).[14]

---

failure to incorporate such evidence in the record in a prior proceeding." 42 U.S.C. § 405(g). The Court may, however, take judicial notice of publicly available resources or guidance documents. *See, e.g.*, *Nebraska v. E.P.A.*, 331 F.3d 995, 998 n.3 (D.C. Cir. 2003); *Brooklyn Heights Ass'n v. Nat'l Park Serv.*, 777 F. Supp. 2d 424, 432 n.6 (E.D.N.Y. 2011).

[14] Plaintiff's reliance on the arbitrary and capricious standard of review under the Administrative Procedure Act ("APA"), 7 U.S.C. § 706, is inappropriate here. *See* Pl.'s Br. at 11-12, 20. Plaintiff's cause of action is predicated solely on the denial of Medicare coverage; therefore, judicial review of the Secretary's final decision is limited to the grant of jurisdiction provided by the Medicare statute and its substantial evidence standard. 42 U.S.C. § 405(g); 42 U.S.C. § 1395ff(b). *See also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (holding that virtually all claims where both the standing and substantive basis of the claim is the Medicare Act must be

## V. ARGUMENT

### A. Plaintiff's Challenges To The Final Decisions Dated November 13, 2015 (M-15-1505) And January 27, 2017 (M-16-10554) Must Be Dismissed For Lack Of Jurisdiction Because The Claims Do Not Meet The AIC Required For Judicial Review Of Medicare Claims.

The instant case involves judicial review of three final decisions of the Secretary related to separate requests for Medicare coverage made by Plaintiff in 2014 and 2016. Given this, the fundamental question is whether Plaintiff has met his burden of establishing that each of the final decisions addressing those requests is properly before the Court. As discussed below, Plaintiff has failed to meet the statutory and regulatory amount in controversy ("AIC") requirements for two of the three final decisions he seeks to challenge and, therefore, Plaintiff's Amended Complaint as to these two decisions should be dismissed for lack of jurisdiction.

As the proponent of federal jurisdiction in this case, Plaintiff bears the burden of establishing subject matter jurisdiction. *Kokkonen v. Guardian Life Ins. Co. of America*, 511 U.S. 375, 377 (1994); *Baruch v. Schmeigelow*, 175 F. App'x 422 (2d Cir. 2006). Among other things, this burden requires Plaintiff to show that his claims satisfy the applicable AIC requirement for judicial review. *McNutt v. Gen. Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936). Here, Plaintiff alleges that Medicare should have paid $473 for a 30-day supply of disposable sensors (M-15-1505) and $1,419 for a 90-day supply of disposable sensors (M-16-10554). A.R. M-15-1505, at 116; A.R. M-16-10554, at 317. These claims fall short of the $1,500 and $1,560 thresholds necessary for a Medicare beneficiary to obtain judicial review in

---

channeled through the agency and decided in accordance with § 405(g)-(h)); *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 78 (2d Cir. 2006) (explaining that "the Secretary's actions [are reviewed] pursuant to the specific provisions of § 405(g) where applicable; [only] where no provision of § 405(g) is on point, we apply the judicial review provisions of the APA . . ."). Furthermore, the APA does not provide an independent basis for federal jurisdiction, *Califano v. Sanders*, 430 U.S. 99, 107 (1977), and, as noted, "§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Ringer*, 466 U.S. at 614-15; *supra* note 1.

2016 and 2017, respectively. 80 Fed. Reg. at 57,828; 81 Fed. Reg. at 65,652.

"When a Medicare plaintiff is unable to meet the statutorily-prescribed judicial amount, jurisdiction is lacking and dismissal is appropriate." *Schwartz v. Medicare*, 832 F. Supp. 782, 790 (D.N.J. 1993). As a result, this Court should dismiss Plaintiff's challenges to the Secretary's final decisions in M-15-1505 and M-16-10554 for lack of jurisdiction. *See Baruch*, 175 F. App'x at 422 (affirming the dismissal of the plaintiff's claim for failure to meet Medicare AIC requirements).

Plaintiff could have aggregated multiple claims to meet the AIC required for judicial review by using 42 C.F.R. § 405.1006(e), which permits aggregation at the ALJ level where certain requirements are met—most critically, that the claims "involve the delivery of similar or related services." 42 C.F.R. § 405.1006(e). Indeed, the regulations permit a beneficiary to request aggregation "within 60 days after receipt of *all the reconsiderations being appealed*," meaning that Plaintiff could have aggregated claims for supplies that were furnished at different time periods. 42 C.F.R. § 405.1006(e)(1)(ii) (emphasis added). *See also id.* (explaining that a request for aggregation may be made in either "the same request for ALJ hearing" or "in multiple requests for an ALJ hearing"). However, there is no evidence in any of the three administrative records that Plaintiff aggregated his Medicare claims below. *See* A.R. M-15-4332, at 133, 137, 282-83,321-29;[15] A.R. M-15-1505, at 79, 82; A.R. M-16-10554, at 248.

A letter enclosed with Plaintiff's request for an extension of time to file his district court appeal of the final decision in M-15-1505 recognized this flaw. *See* A.R. M-15-1505 at 3.

[15] The final decision in M-15-4332 was based on two separate ALJ appeals. *See supra* note 12. Although one of Plaintiff's ALJ appeal requests checked "yes" regarding whether the request involved multiple claims, Plaintiff did not specify which claims were at issue. *See* A.R. M-15-4332, at 321-29. It appears the multiple claims were the disposable sensors furnished on June 18, 2014 and the CGM transmitter furnished on June 27, 2014, not the claims at issue in M-15-1505 or another final decision. *Id.* at 327.

Through counsel, Plaintiff expressed that the claims at issue in M-15-4332 and M-15-1505 "need[ed] to be consolidated in order to meet the federal amount in controversy requirement." *Id.* As the Medicare rules direct, aggregation cannot occur at the judicial review stage. *See Epstein v. Burwell*, No. CV-13-8728, 2014 WL 12591476, at *5 (C.D. Cal. Aug. 5, 2014) (involving a claim under Medicare Part D but discussing the aggregation rules contained at 42 C.F.R. § 405.1006). The Medicare statute, 42 U.S.C. § 1395ff(b)(1)(E)(ii), and 42 C.F.R. § 405.1006 provide for aggregation only when it occurs at the ALJ level of administrative review. The statute directs the Secretary to promulgate regulations allowing aggregation of "appeals." 42 U.S.C. § 1395ff(b)(1)(E)(ii). The term "appeals," however, refers to administrative appeals taken to the Secretary after an initial determination and redetermination by the Medicare contractor. *See* 42 U.S.C. § 1395ff(a)(3)(B)(i), (a)(5)(A)(iv), and (b)(1)(D) (all setting out rules for "appeal" to the Secretary). Moreover, while the regulatory provision's definition section recognizes that aggregated claims are eligible for judicial review, 42 C.F.R. § 405.1006(a), its mechanism for aggregating claims provides for aggregation *only* at the ALJ level. 42 C.F.R. § 405.1006(e)-(f) (setting forth rules for aggregation of claims "for an ALJ hearing"). *Accord Epstein*, 2014 WL 12591476, at *5 ("[I]nterpreting th[e] [definition] provision as authorizing aggregation for the first time in court makes little sense when considered in the full context of § 405.1006," as doing so "would render the aggregation criteria set forth in § 405.1006(e)-(f) a practical nullity."). Consequently, neither 42 U.S.C. § 1395ff(b)(1)(E)(ii) nor 42 C.F.R. § 405.1006 includes any provision authorizing claims to be aggregated for purposes of judicial review where they were not aggregated at the ALJ stage. *See also Epstein*, 2014 WL 12591476, at *5 (deferring to the agency's interpretation and explaining that "[t]his interpretation of the aggregation provisions is also consistent with § 405(g)'s broad jurisdictional bar against claims

that have not been presented for administrative review").

In sum, Plaintiff's Amended Complaint as to the final decisions in M-15-1505 and M-16-10554 must be dismissed for lack of subject matter jurisdiction because neither underlying claim satisfies the monetary threshold for judicial review of Medicare claims. Plaintiff failed to aggregate these claims to meet the AIC during the administrative proceedings, and he cannot do so now.

**B. The Secretary's Denial Of Medicare Coverage In The Decision Dated February 24, 2016 (M-15-4332) Is Supported By Substantial Evidence And Should Be Affirmed.**

The Secretary's final decision dated February 24, 2016, denying Medicare coverage for Plaintiff's CGM transmitter and disposable sensor supplies, is supported by substantial evidence in the record and should be affirmed. While it is possible that Plaintiff has benefitted from use of his CGM, such evidence "do[e]s not factor into the determination of whether the[] items . . . fall within the statutory DME benefit category." A.R. M-15-4332, at 11. To be covered by Medicare, an item or service (including related supplies) must fall under a defined benefit category, must be reasonable and necessary for the diagnosis or treatment of an injury or illness, and must meet all applicable statutory and regulatory requirements. *See* 42 U.S.C. §§ 1395k, 1395x, 1395y(a)(1)(A); 68 Fed. Reg. at 55,635 ("Medicare payment is contingent upon a determination that a service meets a benefit category, is not specifically excluded from coverage, and . . . is 'reasonably necessary.'"). Here, substantial evidence demonstrates that Plaintiff's CGM system does not fit within a Medicare benefit category (DME) and therefore, as the Council found, is non-covered. A.R. M-15-4332, at 10-11. The Secretary's decision in M-15-4332 accords with the Medicare statute and regulations, and is free from legal error.

Among the regulatory requirements for DME is that an item "[i]s primarily and customarily used to serve a medical purpose." 42 C.F.R. § 414.202. CMS has developed

guidance for MACs to aid in determining whether an item satisfies this criterion. Relevant here, the MBPM explains that "precautionary-type equipment" has been traditionally considered "nonmedical in nature" because, even while the equipment "has some remote medically related use," another device achieves the intended medical purpose; thus, precautionary equipment does not traditionally fit within the Medicare benefit category for DME. MBPM, Ch. 15, § 100.1-B; A.R. M-15-4332, at 10. While no NCD specifically addresses CGMs, NHIC has determined that a CGM system does not fit within the DME benefit category because of its precautionary nature. A.R. M-15-4332, at 10.

The Council discussed the validity of NHIC's determination in its decision.[16] As the Council explained, and as detailed in the administrative record, CGM systems—in particular, the CGM utilized by Plaintiff—are not intended to replace a beneficiary's traditional blood glucose monitoring. *Id.* at 10-11, 43, 385 (testimony of Plaintiff confirming that recent articles "state clearly that using a [CGM] you still need to monitor your blood sugar and prick your finger"). Rather, a CGM is used to indicate when a traditional glucose meter reading may be necessary, so that a beneficiary can, after getting an accurate reading of his or her blood glucose, make a therapeutic decision, *id.* at 11; a CGM supplements that process and perhaps makes it easier for many individuals to "spot patterns or trends," *id.* at 385, but does not replace it. *Id.* at 10-11, 385. Consequently, the Council agreed with the classification of Plaintiff's CGM as precautionary, and found that "CGMs (and thus, the sensors and transmitter at issue) do not fall within a defined Medicare benefit category." *Id.* at 11.

The Council's decision is a reasonable conclusion based on this evidence. *See Berry*, 675

[16] Though alleged in his Amended Complaint, Plaintiff since has abandoned the argument that the Council afforded improper deference to NHIC's Policy Article. In any event, the Secretary contends that the Council did not improperly defer to the Policy Article, but rather, followed applicable CMS regulatory criteria and guidance pertaining to the DME benefit category in making its decision.

F.2d at 467. Although Plaintiff argues that his CGM system is "uniformly acknowledged as a medical device," Pl.'s Br. at 14-15, and "the primary means by which [brittle diabetics] control their diabetes," *id.*, the evidence advanced by Plaintiff during the administrative proceedings in M-15-4332 (or even in the administrative proceedings for M-15-1505 and M-16-10554, as discussed separately below) does not demonstrate that his CGM in fact "[i]s primarily and customarily used to serve a medical purpose," as used in this context. 42 C.F.R. § 414.202. As Plaintiff admitted, his CGM system "may help you spot patterns or trends easier," but is not meant to take the place of traditional blood glucose monitoring. A.R. M-15-4332, at 385. The information the Council reviewed from the manufacturer of Plaintiff's CGM system, Medtronic, echoed this understanding. *Id.* at 11 ("The [Medtronic] website further indicates that '[i]t is still required to check blood glucose levels with a fingerstick before therapy adjustment.'"). Accordingly, it cannot be said that Plaintiff's CGM system is either "primarily [or] customarily used" to serve the medical purpose of controlling Plaintiff's diabetes. 42 C.F.R. § 414.202. Instead, Plaintiff's traditional blood glucose monitor is what informs him of when a therapy adjustment is needed and what that therapy adjustment should be, based on an actual reading of his blood glucose. Stated another way, Plaintiff's traditional blood glucose meter is the device primarily and customarily used for the purpose of controlling his diabetes, not his CGM.

The records and opinions of Plaintiff's physician, Dr. Richard Pratley, are unpersuasive to support a different conclusion. *See* Pl.'s Br. at 18-19. In the absence of a controlling coverage document, the first step in the sequential analysis required of the Council was to assess whether Plaintiff's CGM system fit within a Medicare benefit category altogether. *See* 68 Fed. Reg. at 55,635; A.R. M-15-4332, at 10-11. Thus, the question of whether Plaintiff's CGM was reasonable and necessary for the diagnosis or treatment of his illness was not immediately before

the Council. The materials from Plaintiff's physician, which date from 2009, address only Plaintiff's need for the CGM system. For instance, they indicate that Plaintiff uses his CGM along with traditional glucose monitoring, and that Plaintiff has experienced "significant benefit" from doing so.[17] *Id.* at 104, 110-11. However, these opinions do not address whether Plaintiff's use of monitoring via CGM is an accurate or adequate substitute for traditional blood glucose monitoring and/or is the device that primarily controls his diabetes; and thus, these opinions do not support a different conclusion on the basis of the administrative record.

The Council's determination that Plaintiff's CGM is precautionary recognizes that Medicare is a program of defined benefits, and that a beneficiary is not entitled to coverage of every item that may be beneficial. Substantial evidence supports the Council's denial of coverage, and the Secretary's final decision should be affirmed.[18]

### C. The Secretary's Final Decisions Dated November 13, 2015 (M-15-1505) And January 27, 2017 (M-16-10554) Are Supported By Substantial Evidence And Should Be Affirmed.

1. Final Decision Dated November 13, 2015 (M-15-1505)

Should the Court decline to dismiss Plaintiff's challenge to the decision dated November 13, 2015, the decision is supported by substantial evidence. The administrative record

[17] Even if the question of reasonable and necessary was before the Council, Dr. Pratley's determination of the CGM's medical necessity would not be binding as to whether the equipment is covered by Medicare. *See State of N.Y. on Behalf of Bodnar v. Sec'y of Health and Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990); *Goodman v. Sullivan*, 712 F. Supp. 334, 338 (S.D.N.Y. 1989). Similarly, Dr. Pratley's opinion would not be entitled to controlling weight. *See* Pl.'s Br. at 19. While a "treating physician rule" is applicable in Social Security disability cases, *see Office of Vermont Health Access ex rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 450 (D.Vt. 2010), the same rule has not been extended to Medicare cases. *See Keefe*, 71 F.3d at 1064 (2d Cir. 1995); *Diapulse Corp. of Amer. v. Sebelius*, No. 06-CV-2226, 2010 WL 1037250, *7-8 (E.D.N.Y. Jan. 21, 2010) (refusing to apply the rule in a Medicare Part B case).

[18] Plaintiff also submits that, under an arbitrary and capricious standard of review, the Secretary's final decisions are invalid because they conflict with "final [ALJ] decisions rendered in [Plaintiff's] favor . . . and . . . more than 40 other final decisions." As indicated, the appropriate standard of review in this case is substantial evidence under § 405(g). That being said, the fact that other ALJs have ruled in favor of Plaintiff does not mean Plaintiff is entitled to Medicare coverage for his CGM and supplies. The applicable regulations specifically state that ALJ decisions that do not adhere to policy guidance, for instance, the manual instructions and program memoranda discussed in the Secretary's final decisions, are not precedential. 42 C.F.R. § 405.1062(b).

underlying the Council's decision in M-15-1505 is similar to that in M-15-4332, with the exception of CMS' memorandum referring the ALJ decision to the Council, A.R. M-15-1505, at 30-37, and more recent medical notes from another treating physician, Dr. John Leahy. *Id.* at 59-61. After reviewing the record and hearing transcript, the Council concluded that "Medicare does not cover the CGM sensors at issue because they do not fall within the statutory Durable Medical Equipment (DME) benefit category." *Id.* at 21. The Council's decision is supported by substantial evidence and, thus, should be affirmed.

As an initial matter, the Council rejected the ALJ's framing of the issue as whether Plaintiff's CGM usage was medically reasonable and necessary. The Council found that the issue before it was "whether CGMs are covered under the DME benefit," *id.* at 23, an overarching requirement for Medicare coverage of Plaintiff's CGM system and supplies. The Council looked to the Medicare statute, 42 C.F.R. § 414.202, and the MBPM for guidance on the DME criteria. *Id.* at 24. Finding no applicable CMS coverage document, the Council again arrived at the statement in NHIC's Policy Article A33164/A52464 that "'[CGMs] . . . are considered precautionary . . . .'"[19] *Id.* at 26 (citing the Policy Article). The Council then assessed the validity of the MAC's determination, looking to Plaintiff's hearing testimony and information from the manufacturer of Plaintiff's CGM system. *Id.* at 27. In particular, the Council noted Plaintiff's testimony that he still must utilize traditional blood glucose monitoring in order to make therapeutic decisions, as also instructed by Medtronic on its website. *Id.* at 27 (citing http://medtronicdiabetes.com/products/continuous-glucose-monitoring); A.R. M-15-1505, Hearing Transcript, at 12. Given the totality of this evidence, the Council concluded that "since the CGM does not substitute for the existing means of controlling insulin usage, or measure

[19] *See supra* note 16.

blood glucose directly, . . . it merely provides an added precaution and does not itself serve a primary medical purpose." *Id.*

The Council's conclusion is a reasonable interpretation of the record. *See supra* pp. 20-21. Moreover, while Plaintiff submitted more recent information from another treating physician during the administrative proceedings, this information does not go to the question of whether his CGM is non-precautionary. *See* A.R. M-15-1505, at 59-62 (also reflecting that Plaintiff tests his blood glucose "5-9" times daily along with his use of the CGM). Thus, the Council's denial of Medicare coverage is based on substantial evidence, including the applicable Medicare rules and Plaintiff's own statements about his use of the device. That Plaintiff contends his CGM system is the device primarily used for controlling his diabetes, *see* Pl.'s Br. at 14-16, particularly where the record fails to adequately support that conclusion, does not warrant a different result. *See Jones*, 949 F.2d at 59.

2. Final Decision Dated January 27, 2017 (M-16-10554)

Should the Court decline to dismiss Plaintiff's challenge to the decision dated January 27, 2017, this decision is also supported by substantial evidence. The record underlying the Council's decision in M-16-10554 contains a significant amount of information not present in the other administrative records. This information is in the form of journal articles and studies regarding CGMs, *see* A.R. M-16-10554, at 88-101, 456-801, and recent FDA pronouncements regarding glucose monitoring devices. *Id.* at 76-86. The Council reviewed these materials, but concluded that they failed to support a finding that Plaintiff's CGM satisfied the criteria for DME. *Id.* at 9. As detailed below, the Council's decision is supported by substantial evidence, and should be affirmed.

As the Council explained, 42 C.F.R. § 414.202 requires that to be classified as DME, the equipment must be "primarily and customarily used to serve a medical purpose." *Id.* at 11. To

determine whether Plaintiff's CGM satisfied this requirement, the Council examined the evidence submitted by Plaintiff. *See id.* Even while discussing improved accuracy in CGM systems and user benefits, however, this evidence failed to indicate that a CGM (and specifically, Plaintiff's CGM) could be used as a replacement for traditional blood glucose monitoring. *See id.* at 472 ("Throughout the study, subjects were instructed to use CGM data as an adjunct to, and not as a replacement for, . . . fingersticks when making diabetes-related treatment decisions (e.g., insulin dose modifications)." (2007)); 496 ("[I]nadequate sensor accuracy, compared with capillary fingerstick or laboratory reference blood glucose measurements, . . . ha[s] been noted as a hindrance to widespread adoption of [CGMs] . . . ." (2013)); 500-501 (describing using a CGM "as part of [a] routine diabetes management experience," and stating that "CGM does not yet have the point accuracy of the current generation of blood glucose monitors" (2013)); *see also id.* at 504 (describing limited studies regarding the effectiveness of CGM in avoiding severe hypoglycemia (2013)); 523 (noting that "[b]ecause of imprecision . . . and resulting safety concerns, CGM systems to date have received regulatory approval in the United States only for use adjunctive to self-monitored blood glucose" (2014)). Further, the FDA materials submitted by Plaintiff did not address whether Plaintiff's CGM might serve the primary purpose of controlling his diabetes, but rather, only discussed other technologies—an artificial pancreas, *id.* at 12, 22-23, and the Dexcom G5 CGM—which are not the items at issue in this case. *Id.* at 12-13, 16-17. Significantly, the Dexcom G5 CGM has been specifically recognized as DME for the very reason that it **does replace** the traditional fingerstick blood glucose monitoring and can be used to make diabetes treatment decisions, unlike Plaintiff's CGM system. *See supra* note 10.

While Plaintiff asserts that professional medical societies and experts in diabetes care have determined that CGMs serve a primary and customary medical purpose, *see* Pl.'s Br. at 2-4,

14-18, Plaintiff fails to recognize that, in fact, the information he provided during the administrative proceedings supports an opposite conclusion: namely, that a CGM cannot be used primarily to control an individual's diabetes. Indeed, these sources indicate that doing so would be neither safe nor effective for that purpose.[20] Accordingly, the Council's determination that Plaintiff's CGM does not qualify as DME because it is "essentially used as an additional precaution, but not for a primary medical purpose," A.R. M-16-10554, at 11, is supported by substantial evidence in the record, and should be affirmed.

## VI. CONCLUSION

Plaintiff's challenge to the final decisions in M-15-1505, dated November 13, 2015, and M-16-10554, dated January 27, 2017, should be dismissed for failure to meet the amount in controversy required for judicial review. In addition, the Council's decision in M-15-4332, dated February 24, 2016—as well as the decisions in M-15-1505 and M-16-10554, if viewed as properly before this Court—is supported by substantial evidence and the Secretary respectfully requests that the Court deny Plaintiff's Motion, affirm the Council's decisions, and grant judgment in the Secretary's favor.

[20] Of course, the Secretary is cognizant of recent advancements in CGM technologies. *See supra* Part II-B. At present, however, the only CGM that may be safely and effectively used as a replacement for traditional blood glucose monitoring is the Dexcom G5. A.R. M-16-10554, at 16-17.

Dated at Burlington, in the District of Vermont, this 8th day of September, 2017.

Respectfully Submitted,

EUGENIA A.P. COWLES
Acting United States Attorney

By: /s/ *Melissa A. D. Ranaldo*
MELISSA A.D. RANALDO
Assistant United States Attorney
United States Attorney's Office
11 Elmwood Ave., 3rd Floor
P.O. Box 570
Burlington, VT 05402-0570
802-951-6725
melissa.ranaldo@usdoj.gov

Of Counsel:

JEFFREY S. DAVIS
Acting General Counsel

JAN B. BROWN
Acting Chief Counsel, Region I

JILL L. STEINBERG
Assistant Regional Counsel
Department of Health and Human Services
J.F.K. Bldg., Rm. 2250
Boston, MA 02203
(617) 565-2381